

APPENDIX A

**UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT**

LINDA P. SMITH,)	
)	
Plaintiff,)	
)	
v.)	Case No. 22-4012
)	
XAVIER BECERRA, in his official)	
capacity as Secretary of Health and)	
Human Services,)	
)	
Defendant.)	
)	

DECLARATION OF KAREN GRASSO

I, Karen Grasso, hereby declare as follows:

1. I am over the age of 18 and competent to testify herein. I have personal knowledge of the facts set forth below.
2. I am employed by Noridian Healthcare Solutions, LLC (“Noridian”). My job title is Deputy Project Manager.
3. Noridian is a Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services (“CMS”). One of the functions Noridian performs as a contractor is processing claims for reimbursement for Medicare Part B beneficiaries. As Deputy Project Manager, one of my responsibilities is to support the performance of Noridian’s contract to process claims for durable medical equipment.
4. The above-referenced plaintiff, Linda P. Smith, is a Medicare Part B beneficiary for whom Noridian processes claims. My understanding is that Ms. Smith has filed a petition for rehearing in this case, based on Noridian’s denial of Ms. Smith’s claim for reimbursement of Continuous Glucose Monitor (CGM) supplies with a date of service of May 20, 2022 (“the May 2022 claim”). As explained below, Ms. Smith’s May 2022 claim was properly denied as billed

by the CGM supplier, MiniMed Distribution Corp (“MiniMed”). In particular, MiniMed’s failure to append a “CG modifier” to its claim indicated that Ms. Smith did not meet the coverage criteria for a CGM.

5. Providers and suppliers use Healthcare Common Procedure Coding System (HCPCS) codes to report the medical items and services they have provided to Medicare beneficiaries and to bill Medicare for reimbursement of such items and services. HCPCS codes are defined by CMS and are updated throughout the year, as necessary. In addition, CMS identifies “modifiers” that may be appended to HCPCS codes to provide additional information about the services rendered to enable the contractor processing the claim and CMS to determine whether the item or service is covered by Medicare. Modifiers consist of two alphanumeric characters. Modifiers are to be appended to HCPCS codes only if the clinical circumstances justify the use of the modifier.

6. Medicare Administrative Contractors issue Local Coverage Determinations (LCDs) to provide information regarding what items will be covered by Medicare as “reasonable and necessary” under Social Security Act § 1862(a)(1)(A), 42 U.S.C. § 1395y(a)(1)(A). The contractors also issue Local Coverage Articles that provide instructions on how to bill claims and other provider or supplier education attendant to a particular Local Coverage Determination.

7. Local Coverage Determination L33822, available at <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822>, addresses the coverage of glucose monitors. It provides:

To be eligible for coverage of a CGM and related supplies, the beneficiary must meet all of the following coverage criteria (1)-(5):

1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,

2. The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
3. The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of [blood glucose monitor] or CGM testing results; and,
4. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-3) above are met; and,
5. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.

LCD L33822 further states that “[i]f any of the coverage criteria (1-5) are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.” Under “Coding Information,” the LCD indicates that a supplier should use the CG modifier in a Medicare claim for reimbursement for a CGM or CGM supplies to indicate that the “[p]olicy criteria [have been] applied.”

8. Local Coverage Article A52464, available at <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464>, further addresses the coverage of glucose monitors and contains instructions on how suppliers should bill claims for glucose monitors and their supplies. The article provides:

For CGM devices (code K0554) and the supply allowance (code K0553) the CG modifier must be added to the claim line only if all of the CGM coverage criteria (1-5) in the Glucose Monitors LCD are met. The CG modifier must be added to the claim line for an adjunctive CGM (E2102) incorporated into an insulin infusion pump and supply allowance (code A4238) only if all of the CGM coverage criteria (1-5) in the Glucose Monitors LCD and the coverage criteria for an insulin infusion pump as outlined in the External Infusion Pumps LCD (L33794) are met. If any of the coverage criteria are not met, the CG modifier must not be used.

9. Accordingly, pursuant to Local Coverage Determination L33822 and Local Coverage Article A52464, a claim for a CGM or CGM supplies must contain the CG modifier to

indicate the beneficiary's eligibility for those items. A claim for a CGM or CGM supplies that does not contain the CG code will be denied as not reasonable and necessary under the Medicare statute.

10. For the May 2022 claim, MiniMed billed Medicare for CGM supplies furnished to Ms. Smith without including the CG modifier. The information submitted to Noridian thus indicated that Ms. Smith did not meet the coverage criteria for a CGM or for an insulin infusion pump. The May 2022 claim was therefore denied as not reasonable and necessary.

11. If MiniMed erred in submitting the original claim, it should have sought a redetermination of the claim and submitted evidence to Noridian demonstrating that the claim was coverable.

12. On October 4, 2022, an employee in Noridian's customer service department contacted MiniMed to inquire about the May 2022 claim and spoke with Angela Ward, Principal Operations Specialist, Managed Markets. Ms. Ward informed Noridian that the failure to include the CG code was in error. Ms. Ward further advised that MiniMed has called Ms. Smith to explain its billing error and that MiniMed will write off the amount billed for the May 2022 claim. Ms. Smith will not be billed for those supplies. While Noridian denied this claim and MiniMed wrote the amount off, Ms. Smith still received the CGM supplies pursuant to her May 2022 claim.


13. I have reviewed Ms. Smith's claims history. Aside from the May 20, 2022 claim, MiniMed also submitted on Ms. Smith's behalf claims for CGM supplies with dates of service April 20, 2022, June 9, 2022, July 11, 2022, August 3, 2022, and September 6, 2022. Each of those claims has been approved and paid. With the exception of the April 20, 2022 claim, each of these claims included the CG modifier indicating that Ms. Smith met the coverage criteria for

a CGM. The April 20, 2022 claim did not include that modifier and appears to have been erroneously approved and paid. However, Noridian does not intend to change the coverage determination on that claim or seek recoupment of the amount paid.

14. I understand that Ms. Smith has asserted that the denial of her May 2022 claim demonstrates that CMS and its contractors are adhering to an earlier policy of denying claims for CGMs and CGM supplies as not durable medical equipment. As explained above, however, the May 2022 claim was denied for an independent reason. Under current policy, CGMs are durable medical equipment covered by Medicare Part B. We no longer deny claims for CGMs or CGM supplies on the basis that they are not durable medical equipment.

DATED: October 24, 2022

Respectfully submitted,



Karen Grasso



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VIA CM/ECF

October 27, 2022

Mr. Christopher M. Wolpert
U.S. Court of Appeals for the
Tenth Circuit
1823 Stout Street
Denver, CO 80257

RE: *Smith v. Becerra*, No. 22-4012 (10th Cir.)

Dear Mr. Wolpert:

I am writing to clarify and correct statements in the Secretary of Health and Human Services' opposition to plaintiff's petition for rehearing, which was filed on October 25. In the declaration attached to that opposition, Karen Grasso stated that a representative from MiniMed Distribution Corp. informed a customer-service representative from Noridian Healthcare Solutions, LLC "that MiniMed has called Ms. Smith to explain its billing error and that MiniMed will write off the amount billed for the May 2022 claim." Grasso Decl. ¶ 12. The opposition states that "MiniMed has ... represented that it explained the error to plaintiff and will write off the amount billed for the May 2022 claim." Opp. to Reh'g Pet. 9 n.2.

After the Secretary filed the opposition and declaration, counsel for plaintiff contacted the undersigned and informed him that plaintiff had not spoken with MiniMed regarding the matter. Counsel for the Secretary immediately inquired into the issue. The Noridian representative contacted MiniMed again yesterday and was informed

that MiniMed had indeed called plaintiff on October 5 and October 18 with the intent to explain the billing error and advise Ms. Smith that she would not be required to pay for the supplies at issue, but was not able to reach plaintiff.

Any imprecision or inaccuracy concerning this matter has no bearing on the legal question addressed in the government's response to the rehearing petition. As Ms. Grasso's declaration and the brief explain, plaintiff's May 2022 claim was denied for reasons unrelated to the 2017 policy at issue in this case, which has been rescinded and has not been reimplemented. In light of the new information, however, we want to correct any possible inaccuracy in our opposition.

Sincerely,

s/ Joshua M. Koppel

Joshua M. Koppel
Attorney
Civil Division, Appellate Staff
U.S. Department of Justice

cc: Counsel (via CM/ECF)